# Oximeter Clinician's Operation Manual





Catalog Number 1850 Version 15, March 2005 © 2005 Smiths Medical family of companies. All rights reserved.

# **Revision History**

Version	Release Date	Change(s)
15	March, 2005	Removed the statement that claims that pressing the I.D./Clear key will cause printing to stop (page 7-6) Added 1310 DOT reusable finger sinsor and 1311 sensor tape. Updated Smiths family copyright statement. Updated registered trademark statements. Changed font to Myriad Pro. Added this Revision History page. Updated the Smiths logo to include a * symbol.

Smiths and BCI and Comfort Clip are trademarks of the Smiths Medical family of companies.

Microfoam is a trademark of the 3M Company.

The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

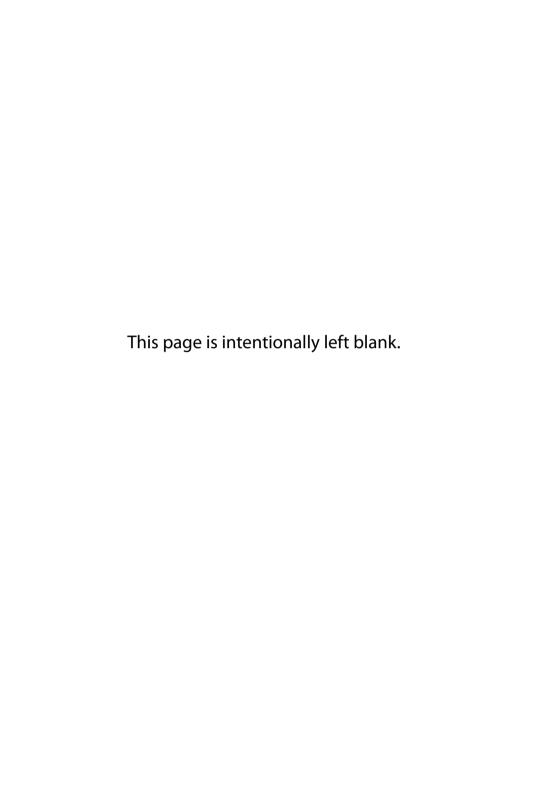
# **Table of Contents**

Chapter 1: Introduction1-1
Proprietary Notice
Chapter 2: Monitor Features2-1
About the Manuals
Chapter 3: Controls 3-1
Chapter 4: Operating Instructions4-1
Unpacking the Monitor
Checking the Sensor and Oximetry Cable
Alerts

## Table of Contents

Chapter 5: Changing the Monitor's Settings	5-1
Silencing Alarm and Alert Tones	5-1 5-1 5-2
Chapter 6: Patient Numbers and Trend Data	6-1
Description Manually Incrementing the Patient Number Viewing Trend Data Clearing Trend Data	6-1 6-1
Chapter 7: Printer	7-1
Description	
Chapter 8: Operating Modes	8-1 8-2 8-3 8-4 8-6 8-6 8-8
PC Communication Setup Transferring Sleep Study Data to a PC	
Chapter 9: Charging the Monitor	9-1

Chapter 10: Maintenance	10-1
Schedule of MaintenanceCorrecting the SENSOR Alert	
Chapter 11: Troubleshooting	11-1
Chapter 12: Optional Supplies and Accessories	12-1
Ordering Information	12-2
Chapter 13: Specifications	13-1
Oximeter	13-1



# **Chapter 1: Introduction**

# **Proprietary Notice**

Information contained in this document is copyrighted by Smiths Medical PM, Inc. and may not be duplicated in full or part by any person without prior written approval of Smiths Medical PM, Inc. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain, and order spare parts for the device supplied. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate regarding any specification.

## **Warranty**

#### **Limited Warranty**

Seller warrants to the original purchaser that the Product, not including accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling for two years from the date of shipment to the original purchaser.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling for one year from the date of shipment to the original purchaser (USA only).

#### **Disclaimer of Warranties**

THE FOREGOING EXPRESS WARRANTY, AS CONDITIONED AND LIMITED, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

#### Chapter 1: Introduction

Seller disclaims responsibility of the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. This disclaimer is dictated by the many elements which are beyond Seller's control, such as diagnosis of patient, conditions under which the Product may be used, handling of the Product after it leaves Seller's possession, execution of recommended instructions for use and others.

#### **Conditions of Warranty**

This warranty is void if the Product has been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

#### Limitation of Remedies

The original purchaser's exclusive remedy shall be, at Seller's sole option, the repair or replacement of the Product. THIS IS THE EXCLUSIVE REMEDY. In no event will Seller's liability arising out of any cause whatsoever (whether such cause is based on contract, negligence, strict liability, tort or otherwise) exceed the price of the Product and in no event shall Seller be responsible for consequential, incidental, or special damages of any kind or nature whatsoever, including but not limited to, lost business, revenues, and profits.

#### **Warranty Procedure**

To obtain warranty service in the USA, you must request a Customer Service Report (CSR) number from Technical Service. Reference the CSR number when returning your Product, freight and insurance prepaid, to:

Smiths Medical PM, Inc. Phone: 1-800-558-2345 N7 W22025 Johnson Drive Fax: 262-542-3325

Waukesha, WI 53186-1856

Seller will not be responsible for unauthorized returns or for loss or damage to the Product during the return shipment. The repaired or replaced Product will be shipped, freight prepaid, to Purchaser.

To obtain warranty information outside of the USA, contact your local distributor.

Keep all original packing material, including foam inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from Smiths Medical PM. Inc.

Damages occurred in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

## **CE Notice**

Marking by the symbol  $C \in O_{0473}$  indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd. Phone: (44) 1923 246434 Colonial Way, Watford, Herts, Fax: (44) 1923 240273

UK, WD24 4LG

# **Definition of Symbols**

Symbol	Definition	
<b>†</b>	Type B equipment	
$\triangle$	Attention, consult accompanying documents	
À	Refer servicing to qualified service personnel	
Ø	Alarm Silence	
<b>®</b>	Non AP Device	
0	On	
Ò	Off	
<u>P1</u>	ID Clear	
<b>▲ ▼</b>	Up and Down Keys	
	Alarm Volume	
<b>Y</b>	Pulse Volume	
Σ	Use By	
REF	Catalog Number	
	Date of Manufacture	
SN	Serial Number	
$\bigcirc$	Moisture Sensitive	

## Warnings, Cautions, and Notes

Keyword	Definition	
⚠warning!	Tells you about something that could hurt the patient or hurt the operator	
CAUTION!	Tells you about something that could damage th monitor	
NOTE!	Tells you other important information	



WARNING! These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the Oximeter. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.



WARNING! Federal law (USA) restricts the use or sale of this device by, or on the order of, a physician.



WARNING! Do not use this device in the presence of flammable anesthetics.



WARNING! Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.



WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.



WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.



WARNING! When attaching sensors with Microfoam<sup>\*1</sup> tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

1. Microfoam is a registered trademark of the 3M Company.



WARNING! Connect the AC power cord to a grounded, threewire outlet. Failure to comply may compromise patient isolation.



WARNING! In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.



WARNING! Patient safety can be compromised by the use of a power supply not supplied by Smiths Medical PM, Inc. Use only the power supply included with your monitor, or one approved by Smiths Medical PM, Inc.



WARNING! When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e. IEC 950 for data processing equipment or IEC 601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 601-1-1 systems requirements. Anyone connecting additional equipment to the signal input port or signal output port configures a medical system, and therefore, is responsible that the system complies with the requirements of the system standard IEC 601-1-1.



WARNING! IEC 950 approved equipment must be placed outside of the patient environment. The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.

Example of the patient environment. The dimensions are not prescriptive.

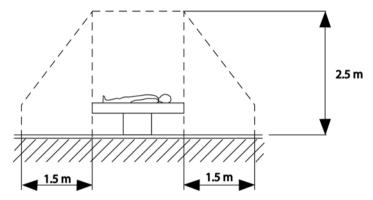


Figure 1-1: Patient Environment (side)

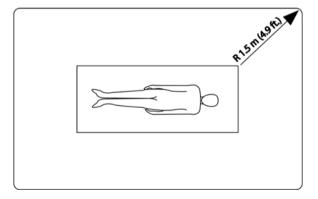


Figure 1-2: Patient Environment (top)

CAUTION! The monitor is equipped with an internal rechargeable battery. Do not attempt to remove or replace the internal rechargeable battery.

Refer servicing to qualified personnel.

CAUTION! Ensure the monitor's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor. Contact the Smiths Medical PM, Inc. service department or your local distributor for help.

CAUTION! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid. Evidence that liquid has been allowed to enter the monitor voids the warranty.

CAUTION! This device is intended for use by trained healthcare professionals. The operator must be thoroughly familiar with the information in this manual before using the device.

CAUTION! Monitors not in use must be fully charged at least every five months, otherwise the battery will no longer be able to accept a charge.

CAUTION! Connect only the printer cable specifically intended for use with this device (see Optional Supplies and Accessories).

CAUTION! Failure to charge the monitor while it is not being used may shorten the battery life. Charge the monitor while it is not being used to ensure the longest battery life.

CAUTION! Do not attempt to stand the oximeter upright when not using the protective rubber boot. Position the oximeter on its back.

NOTE! Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electrosurgery equipment.

NOTE! Operation of this device may be adversely affected in the presence of computed tomography (CT) equipment.

NOTE! Use only SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device

NOTE! SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

NOTE! Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and fluorescein may adversely affect the accuracy of the SpO<sub>2</sub> reading.

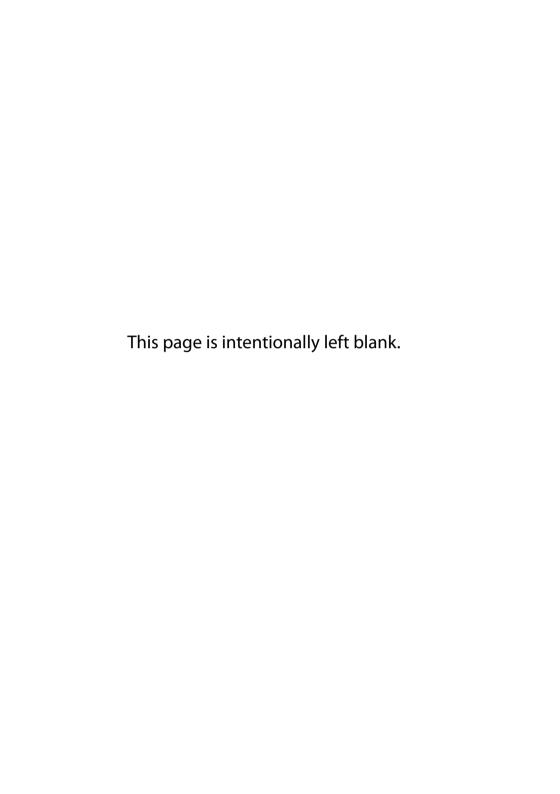
NOTE! Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate  $SpO_2$  and pulse rate readings.

NOTE! Remove fingernail polish or false fingernails before applying SpO<sub>2</sub> sensors. Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.

NOTE! Batteries are not user replaceable.
Service Personnel: Follow local governing ordinances and recycling instructions regarding disposal or recycling of device

components, including batteries.

NOTE! Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.



# **Chapter 2: Monitor Features**

#### **About the Manuals**

The Clinician's Operation Manual provides installation, operation, and maintenance instructions for the health-care professional trained in monitoring respiratory and cardiovascular activity.

The Home-Use Instruction Book provides operation and maintenance instructions for the home-use caregiver. The home-use caregiver is assumed to be trained in oximeter use by a doctor or other health-care professional. The Home-Use Instruction Book supplements, and does not replace, training provided by a health-care professional in oximeter use.

# **Theory of Operation**

The oximeter determines  $\mathrm{SpO}_2$  and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

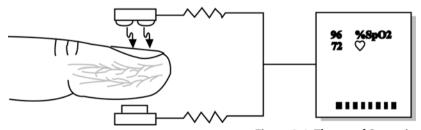


Figure 2-1: Theory of Operation

The oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and  $\mathrm{SpO}_2$ ) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

#### Intended Use

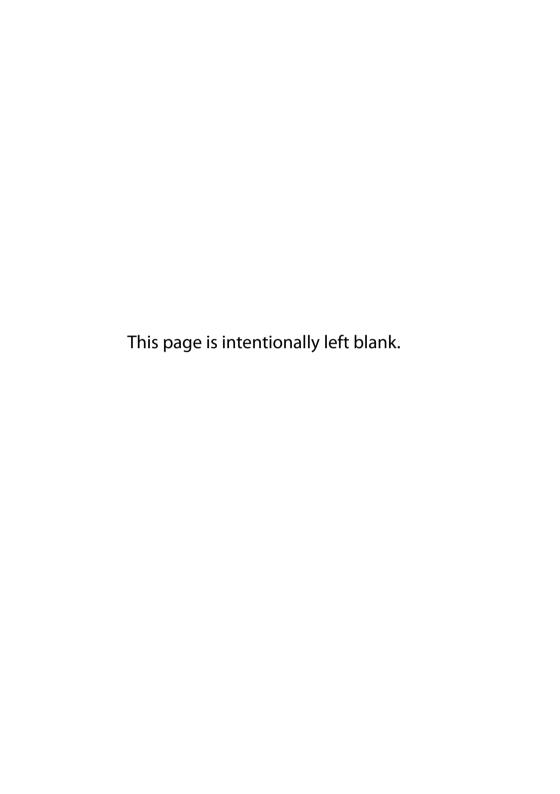
The Oximeter provides fast, reliable  $SpO_2$ , pulse rate, and pulse strength measurements. It may be used in the hospital or clinical environment, during emergency air or land transport, or for in-home use. The oximeter will operate accurately over an ambient temperature range of 32 to  $104^\circ$  F (0 to  $40^\circ$  C). The oximeter works with all BCI $^\circ$  oximetry sensors providing  $SpO_2$  and pulse rate on all patients from neonate to adult (see section *Choosing the Sensor* under *Attaching the Sensor to the Patient*).

The oximeter permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The oximeter has three modes of operation: Clinician Mode, Home-Use Mode, and Sleep Study Mode. Clinician Mode aids the health care professional in monitoring patient activity. The Home Use Mode permits the home-use caregiver to monitor a patient within the home environment. Finally, Sleep Study Mode allows the health care professional to record sleep study data which may later be transferred to a PC and analyzed.

#### **Monitor Features**

- Provides fast, reliable SpO<sub>2</sub>, pulse rate, and pulse strength measurements on any patient, from neonates to adults.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, during emergency air or land transport, or for in-home use.
- Portable and lightweight. Weighs only 19 ounces (539 grams).
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses an internal, rechargeable battery.
- Battery life is approximately 24 hours in continuous use. Battery fully charges in about 6 hours.
- Bright, easy-to-read LED displays indicate  $SpO_2$  and pulse rate measurements. Brightness is user-adjustable.
- An eight-segment LED bar graph indicates pulse strength.
- Positive identification of SpO<sub>2</sub> or pulse rate alarm. Adjustable high and low alarm limits for SpO<sub>2</sub> and pulse rate measurements.
- Adjustable volume (including off) alarm and alert tones.
- Adjustable volume (including off) "beep" sounds with each pulse beat. Pitch of pulse "beep" corresponds to SpO<sub>2</sub> value.

- Low battery indicator lights when about 30 minutes of battery use remains.
- Connects to an optional external printer. Prints less than 15 minutes of trend data in a tabular format, or more than 15 minutes of trend data in a graphic format.
- SpO<sub>2</sub> and pulse rate averaging settings are user-selectable.
- Trend view allows operator to view previous patient history.
- Home-use mode allows a home-use caregiver to monitor a patient at home.
- Sleep study mode allows the health care professional to record the SpO<sub>2</sub> and Heart Rate values of a patient every 4 seconds for up to 12 hours.
- Sleep study mode allows the health care professional to output the data to a PC for further analysis.



# **Chapter 3: Controls**

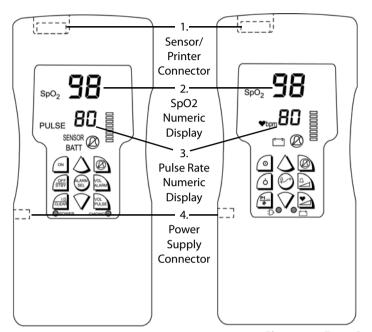


Figure 3-1: Front Panel

#### 1. Sensor /Printer Connector

The sensor connects here, or an oximetry cable can be connected between the monitor and the sensor. The printer is also connected here.

#### 2. SpO<sub>2</sub> Numeric Display

A number shows the patient's  $SpO_2$  value in percent. Dashes (---) mean the monitor is not able to calculate the  $SpO_2$  value.

## 3. Pulse Rate Numeric Display

A number shows the patient's pulse rate value in beats per minute. Dashes (---) mean the monitor is not able to calculate the pulse rate value.

#### 4. Power Supply Connector

The AC power supply connects here.

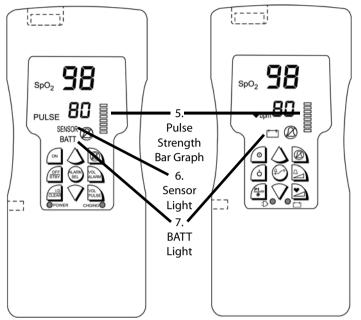


Figure 3-2: Front Panel

#### 5. Pulse Strength Bar Graph

The pulse strength bar graph "sweeps" with the patient's pulse beat. The height of the bar graph tells the strength of the patient's pulse.

## 6. Sensor Light

SENSOR flashes on and off when the sensor is not connected to the monitor, the sensor is not attached to the patient, or the sensor is not properly attached to the patient.



WARNING! While SENSOR is flashing, the monitor cannot measure the patient's SpO<sub>2</sub> or pulse rate. You must immediately check the patient's condition. After you have checked the patient's condition, you must correct the SENSOR alert.

## 7. BATT Light

BATT flashes on and off when about 30 minutes of battery use remains. The monitor will work until the battery becomes very weak. When the battery becomes very weak, the monitor will turn itself off.



WARNING! When BATT flashes, you must immediately charge the monitor's battery. Otherwise, the monitor turns itself off about 30 minutes after BATT begins to flash.

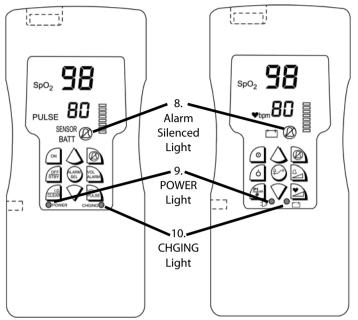


Figure 3-3: Front Panel

# 8. Alarm Silenced Light

The alarm silenced light flashes on and off when the alarm and alert tones are silenced for two minutes. The alarm silenced light remains on when the alarm and alert tones are silenced indefinitely (until canceled or until the monitor is turned off).

#### 9. POWER Light

POWER light is green when the power supply is attached.

#### 10. CHGING Light

The CHGING light is yellow when the battery is fast charging.

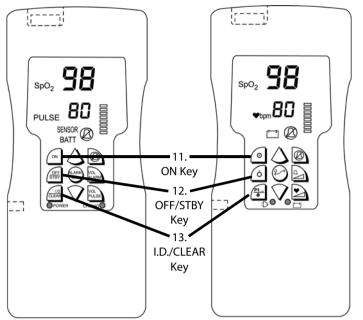


Figure 3-4: Front Panel

#### 11. ON Key

Pressing ON turns on the monitor.

#### 12. OFF/STBY Key

Pressing OFF/STBY turns off the monitor.

#### 13. I.D./CLEAR Key

While the sensor is connected to the monitor: Pressing I.D./CLEAR increases the patient number by one; the patient number is briefly displayed in the  ${\rm SpO}_2$  digits. Pressing and holding I.D./CLEAR for about six seconds clears all trend data and sets the patient number to 1.

While the sensor is not connected to the monitor: Pressing I.D./CLEAR causes the monitor to enter the trend view mode (two bar graph segments flash to indicate trend view mode.) During trend view mode, the last valid measurement for each patient number can be shown by pressing the  $\triangle$  or  $\nabla$  keys. The display shows Pn (n = patient number) then the measurement corresponding to that patient number. If, after 20 seconds, no keys are pressed, the monitor exits the trend view mode.

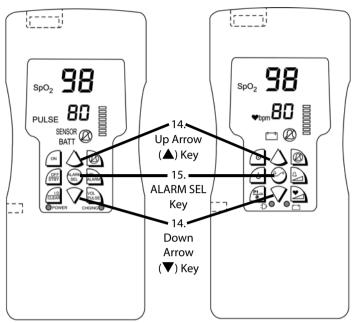


Figure 3-5: Front Panel

#### 14. ▲ and ▼ Keys

The  $\triangle$  and  $\nabla$  keys are used to adjust up and down the following settings: brightness of the display; alarm limits; trend view patient numbers; SpO<sub>2</sub> and pulse rate averaging.

# 15. ALARM SEL Key

Pressing ALARM SEL cycles through each of the alarm limits for setting.

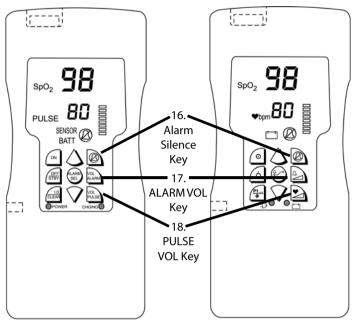


Figure 3-6: Front Panel

# 16. Alarm Silence Key

Momentarily pressing the Alarm Silence key silences the alarm tone for two minutes. Pressing and holding the alarm silence key for about three seconds silences the alarm tone indefinitely (until canceled or until the monitor is turned off).

#### 17. ALARM VOL Key

Pressing ALARM VOL key changes the alarm volume from soft to loud or loud to soft.

#### 18. PULSE VOL Key

Pressing the PULSE VOL key changes the pulse "beep" volume.

NOTE! The pulse volume is stored after the monitor is turned off.

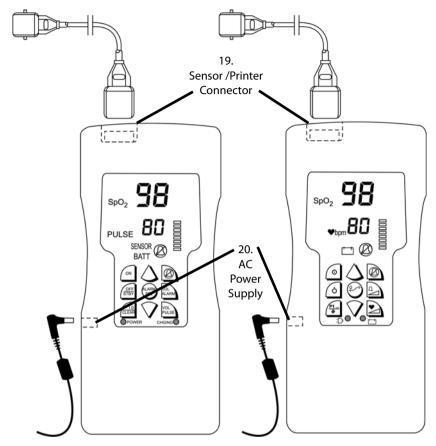


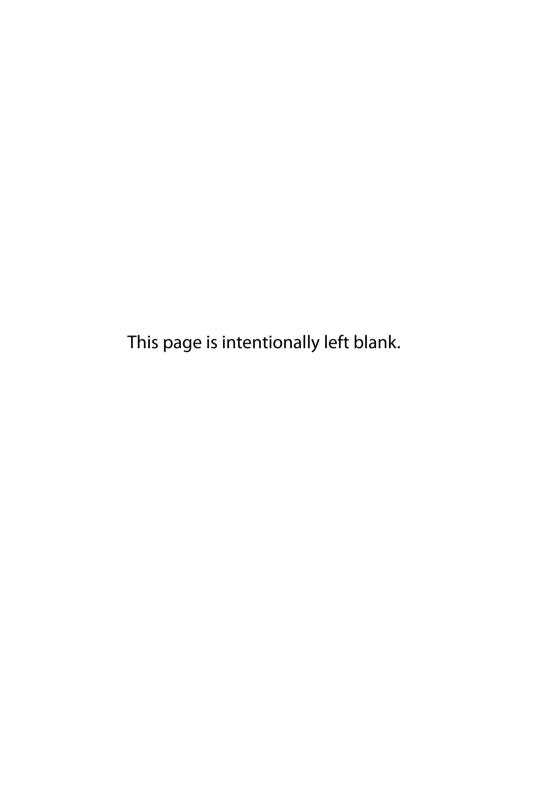
Figure 3-7: Front Panel

#### 19. Sensor /Printer Connector

An optional printer can be connected for printing trend data. See *Printer* section for more printer options.

# 20. AC Power Supply

AC power supply connects here.



# **Chapter 4: Operating Instructions**

## **Unpacking the Monitor**

- Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
- 2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

#### **AC Power**

CAUTION! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. service department, or your local distributor, for help.

Refer also to chapter 12, Optional Supplies and Accessories to verify the proper AC power supply for your application.

NOTE! Do not plug the monitor into an outlet controlled by a wall switch.

- 8210: AC power supply 105-125V
- 8212: AC power supply 230V 50/60Hz
- 8216: AC power supply 100V 60Hz

NOTE! When using AC power, the Oximeter is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

NOTE! Ensure the device's AC rating is correct for the AC voltage at your installation site before using the monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. service department or your local distributor for help.

# Attaching the Sensor to the Patient

What you need to know about attaching the sensor to the patient:



WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.



WARNING! When attaching sensors with Microfoam® tape, do not stretch the tape or attach the tape too tightly. Tape applied too tightly may cause inaccurate readings and blisters on the patient's skin (lack of skin respiration, not heat, causes the blisters).

Attaching the patient to the monitor requires these steps:

- 1. Choose the sensor.
- 2. Check the sensor and oximetry cable.
- Clean or disinfect the sensor if using the reusable type. (Disposable sensors are for single-patient use and do not require cleaning or disinfecting.)
- 4. Attach the sensor to the patient.

## **Choosing the Sensor**

Choose the appropriate sensor from the following chart.

Patient	Site	Description
Adult	Finger	3044: Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip* 1310: D.O.T. Reusable Oximetry Sensors
>45 Kg	Finger or Toe	3043: Sensor, Universal "Y" 1300: Sensor, Disposable, Adult, Finger
	Ear	3078: Sensor, Ear
Pediatric 15-45 Kg	Finger	3044: Sensor, Reusable, Adult 3444: Sensor, Reusable, Comfort Clip* 3178: Sensor, Reusable, Pediatric
	Finger or Toe	3043: Sensor, Universal "Y" 1301: Sensor, Disposable, Pediatric, Finger
	Ear	3078: Sensor, Ear
Infant 3-15 Kg	Hand or Foot Toe Finger or Toe	3043: Sensor, Universal "Y" 3025: Sensor, Wrap, Infant 1303: Sensor, Disposable, Infant
Neonate <3 Kg	Hand or Foot Foot	1302: Sensor, Disposable, Neonate 3026: Sensor, Wrap, Neonate

#### Care and Handling of the Sensor



WARNING! Misuse or improper handling of the sensor and cable could result in damaging of the sensor. This may cause inaccurate readings.

Hold the connector rather than the cable when connecting or disconnecting the finger sensor to the device as shown in Figure 4.1.

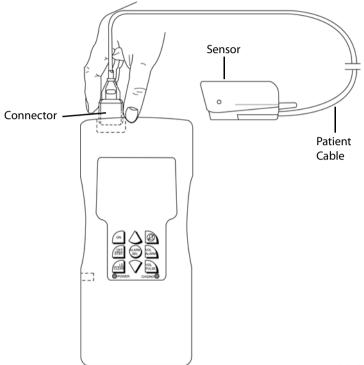


Figure 4-1: Hold the Connector

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor.

When placing the sensor on the patient, allow the cable to lay across the palm of the hand and parallel to the arm of the patient as shown in Figure 4.2.

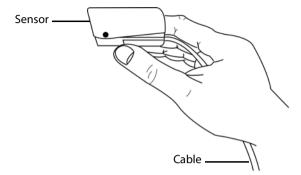


Figure 4-2: Finger Sensor

Upon completion of patient monitoring, detach the sensor as shown in Figure 4.1 and loosely coil the finger sensor cable.

#### **Checking the Sensor and Oximetry Cable**

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the sensor and oximetry cable are working properly.

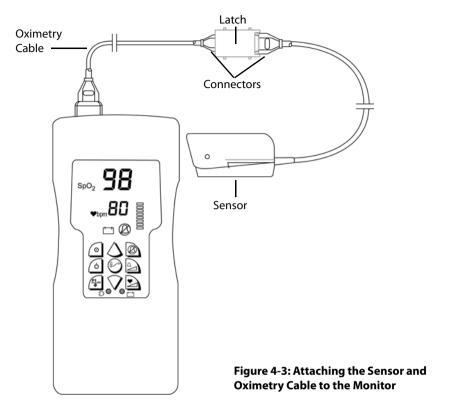


WARNING! Using a damaged sensor may cause inaccurate readings. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help.



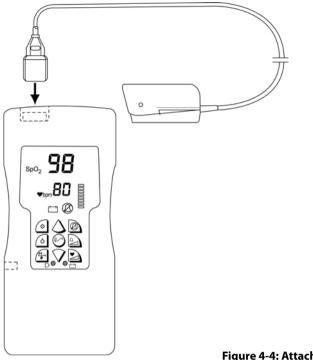
WARNING! Using a damaged oximetry cable may cause inaccurate readings. Inspect the oximetry cable. If the oximetry cable appears damaged, do not use it. Contact your authorized repair center for help.

- 1. Carefully inspect the sensor to make sure it does not appear damaged.
- 2. If using the oximetry cable, carefully inspect the oximetry cable to make sure it does not appear damaged.



#### 3. If using the oximetry cable:

- a. If the sensor is not already connected to the oximetry cable, connect the sensor to the oximetry cable as shown. Push the connectors together firmly and close the latch to secure the connectors.
- b. If the oximetry cable is not already connected to the monitor, connect the oximetry cable to the monitor as shown. Push the connector firmly into the monitor.



- Figure 4-4: Attaching the Sensor to the Monitor
- 4. If not using the oximetry cable: Connect the sensor to the monitor as shown. Push the connector firmly into the monitor.
- 5. If the monitor is not already on, press the ON key to turn on the monitor.

6. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:



WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.

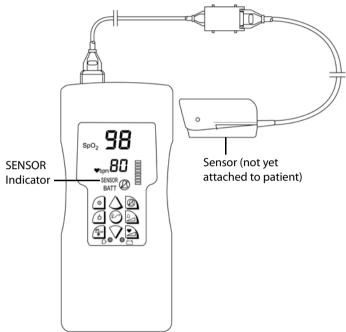


Figure 4-5: Checking the Integrity of the Sensor, Oximetry Cable, and Oximeter

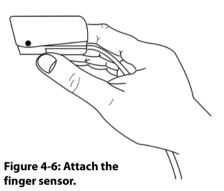
- a. Make sure the red light in the sensor is illuminated.
- b. Make sure the SENSOR indicator is flashing as follows:

NOTE! Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.

#### **Chapter 4: Operating Instructions**

- For "Y" sensors, wrap sensors, and disposable sensors: Align the sensor's red light with the detector so they are less than 1/8 inch away from each other. Make sure the SENSOR indicator is flashing on the oximeter.
- For the finger sensor and ear sensor: Make sure the SENSOR indicator is flashing on the oximeter.
- 7. You are now ready to attach the sensor to the patient.

Attach the finger sensor to the patient as shown. Be sure to fully insert the patient's finger into the sensor. For patients with long fingernails, use the universal "Y" sensor.



### Cleaning or Disinfecting the Sensors

Clean or disinfect reusable sensors before attaching to a new patient.



WARNING! Do not autoclave, ethylene oxide sterilize, or immerse the sensors in liquid.

CAUTION! Unplug the sensor from the monitor before cleaning or disinfecting.

Clean the sensor with a soft cloth moistened in water or a mild soap solution. To disinfect the sensor, wipe the sensor with isopropyl alcohol.

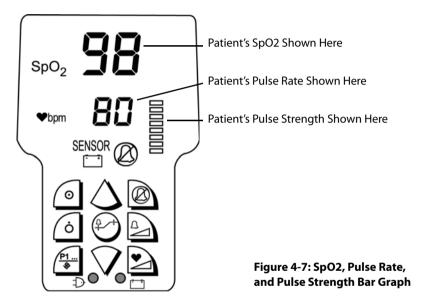
#### **Turning On the Monitor**

To turn on the monitor:

1. Press the ON key.

When turned on, the monitor does the following:

- The pulse strength bar graph segments light one at a time.
- The monitor's software revision is momentarily displayed.
- The patient number is momentarily displayed.
- The monitor is in Clinician Mode.



2. After a few seconds the % SpO<sub>2</sub> value, pulse rate, and pulse strength bar graph should be shown. If not, see the *Troubleshooting* section for help.

3. The monitor has available three averaging settings for SpO₂ and pulse. To change the averaging setting, press and hold the ▼ arrow key while turning on the monitor. While holding the ▼ key, press the ▲ key to scroll through the following averaging selections:

SPO <sub>2</sub> AVERAGING	PULSE AVERAGING
4	8
8	8
16	8
16	16

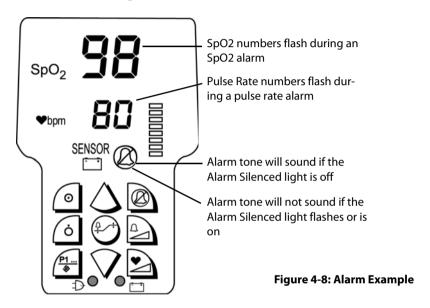
NOTE!  $SpO_2$  averaging is the number of pulse beats over which the  $SpO_2$  value is averaged; pulse averaging is the number of seconds over which the pulse value is averaged.

#### **Alarms**

Alarms warn you about an abnormal patient condition.

#### An alarm turns on when:

- the patient's SpO<sub>2</sub> reading matches or exceeds the SpO<sub>2</sub> alarm range, or
- the patient's pulse rate reading matches or exceeds the pulse rate alarm range.



#### During an alarm:

- the numbers flash that correspond to the alarm.
- the alarm tone sounds, if not silenced. The alarm tone sounds like a siren: dee, doo, dee, doo.

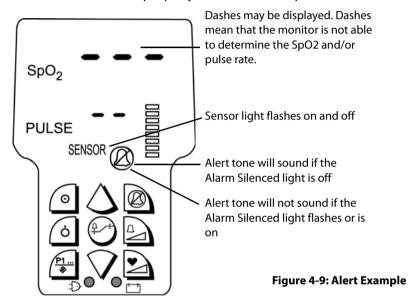
NOTE! Both the  ${\rm SpO_2}$  and pulse rate numbers will flash if both readings match or go beyond their alarm range.

#### **Alerts**

An alert warns you about an abnormal monitor condition.

#### An alert turns on when:

- the sensor is not connected to the monitor, or
- the sensor is not attached to the patient, or
- the sensor is not properly attached to the patient.



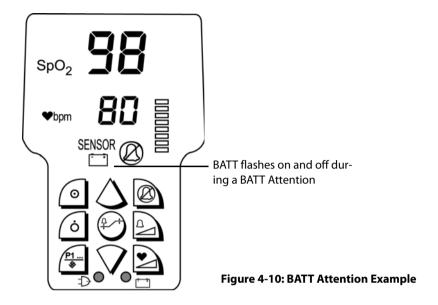
#### During an alert:

- the SENSOR light flashes.
- the alert tone sounds, if not silenced. The alert tone is a singletone sound with a pause: beep beep, pause, beep beep.



WARNING! While SENSOR is flashing, the monitor cannot measure the patient's  $SpO_2$  or pulse rate. You must immediately check the patient's condition. After you have checked the patient's condition, you must correct the SENSOR alert. See *Correcting the Sensor Alert* in the *Maintenance* section for help.

#### **BATT Attention**



#### During the BATT attention:

- a short burst of beeps sounds every 30 seconds.
- · the BATT light flashes on and off.



WARNING! When BATT flashes, you must immediately charge the monitor's battery. Otherwise, the monitor turns itself off about 30 minutes after BATT begins to flash. See *BATT attention* in the *Troubleshooting* section for help.

#### **Turning Off the Monitor**

Turn off the monitor when you are not monitoring a patient.

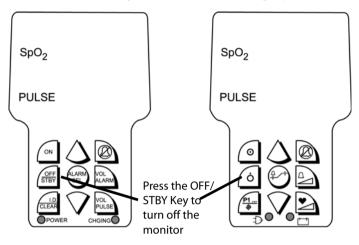


Figure 4-11: Turning Off the Monitor

To turn off the monitor, press the OFF/STBY key.

# Checking the Monitor's Performance

Pulse oximeters do not require user calibration. If checking the function of the device is desired, an optional Oximeter/ECG Patient Simulator (Smiths Medical PM catalog number 1606) is available as an accessory. The simulator attaches to the oximeter in place of the sensor or oximetry cable. It provides a known  $SpO_2$  and pulse rate signal to the oximeter. This allows the oximeter's performance to be checked.

NOTE! The 1606 Oximeter/ECG Patient Simulator does not calibrate the monitor; the monitor does not require calibration. The 1606 provides a known  ${\rm SpO}_2$  and pulse rate to the monitor that allows you to check the monitor's performance.

NOTE! Follow the instructions included with the Oximeter/ECG Patient Simulator.

# **Chapter 5: Changing the Monitor's Settings**

#### **Silencing Alarm and Alert Tones**

The alarm and alert tones can be silenced for two minutes or indefinitely (until canceled or until the monitor is turned off).

- To silence the alarm and alert tones for two minutes, momentarily
  press the alarm silence key. If alarm and alert tones were already
  silenced, you must press the alarm silence key again. The alarm
  silenced indicator flashes during the two-minute time-out.
- To silence the alarm and alert tones indefinitely, press and hold the alarm silence key for about three seconds. The alarm silenced indicator lights steady while alarms are silenced indefinitely.
- 3. To cancel either the indefinite or the two-minute alarm and alert tone silenced condition, momentarily press alarm silence key; the alarm silenced indicator turns off.

#### **Changing the Alarm and Alert Tone Volume**

The alarm and alert tones sound at one of two volumes: soft or loud.

To change between soft and loud volume, press the ALARM VOL key.

#### Changing the Brightness of the Display



WARNING! Adjusting the display too dim may cause the display to be difficult to read in bright light. Make sure the display is bright enough to be seen under all light conditions.

Use the  $\triangle$  or  $\nabla$  keys to change the brightness of the display:

- To increase the brightness of the display, press the ▲ key.
- To decrease the brightness of the display, press the ▼ key.

#### **Changing the Pulse Beep Volume**

A "beep" tone sounds with each pulse beat. The volume of the "beep" can be positioned to three settings: soft, loud, and off. To adjust the volume to the 'off' setting, push the PULSE VOL key once. From the 'off' setting, set the volume to 'soft' by pressing the key once, or press the key twice in quick succession to set the volume to 'loud'.

# **Changing the Alarm Limits**

Each measurement, SpO<sub>2</sub> and Rate, has a high and low alarm limit setting.

Press the ALARM SEL key until the alarm limit you want to change is shown, then press the  $\triangle$  or  $\nabla$  key to increase or decrease the setting.

ALARM SEL KEY PRESS	DISPLAY	ALARM LIMIT
First press.	 H1	= High SpO <sub>2</sub> alarm limit. (Example only.)
Second press.	85 Lo	85 = Low SpO <sub>2</sub> alarm limit. (Example only.)
Third press.	H I 155	155 = High pulse rate alarm limit. (Example only.)
Fourth press.	Lo 50	50 = Low pulse rate alarm limit. (Example only.)
Fifth press.	<b>97</b> 74	97 = SpO <sub>2</sub> measurement. (Example only.) 74 = Pulse rate measure- ment. (Example only.)

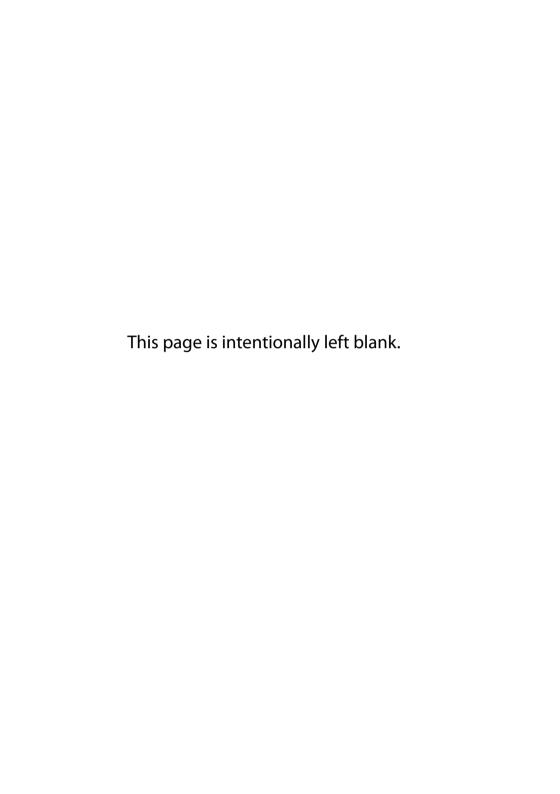
NOTE! " - - - " in the display means the limit is set to off.

NOTE! Alarm limits are non-overlapping. You cannot set the high alarm equal to or lower than the low alarm and you cannot set the low alarm equal to or higher than the high alarm.

NOTE! While setting alarm limits, if no keys are pressed for twenty seconds, the alarm limit setting mode is exited and the SpO<sub>2</sub> and pulse rate measurements are shown.

NOTE! Alarms are not active while setting alarm limits; however, alarms are active as soon as you exit the alarm limit setting mode.

NOTE! The low  $\mathrm{SpO}_2$  alarm limit minimum test value is 80. If an operator changes the low  $\mathrm{SpO}_2$  alarm limit to a value less than 80, and a power down - power up sequence takes place, a minimum value of 85 takes the place of the operator entered value.



# **Chapter 6: Patient Numbers and Trend Data**

#### Description

Whenever the monitor is on, it stores one  $SpO_2$  and one pulse rate reading every thirty (30) seconds. The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 24 hours of run-time.

Trend data is saved for each patient number. When you turn on the monitor, the patient number is automatically incremented and displayed during the power-up sequence if valid trend data was collected from the previous patient. If no valid trend data was collected from the previous patient, the patient number is displayed only and is not incremented. The monitor remembers all the trend data and all the patient numbers for up to 99 patients and 24 hours of run-time.

Trend data for any patient can be viewed on the monitor. Trend data for all patients can be printed on the optional printer.

NOTE! See *Printer* section for information on printing trend data.

#### **Manually Incrementing the Patient Number**

- 1. The SpO<sub>2</sub> sensor must be connected to the monitor. If the SpO<sub>2</sub> sensor is not connected to the monitor, connect the SpO<sub>2</sub> sensor.
- Press the I.D./CLEAR key to increment the patient number. The new patient number is momentarily displayed and trend data for the new patient is automatically saved.

#### **Viewing Trend Data**

- 1. The SpO<sub>2</sub> sensor must be disconnected from the monitor. If necessary, disconnect the SpO<sub>2</sub> sensor from the monitor.
- 2. Press the I.D./CLEAR key; the following sequence occurs:

#### Chapter 6: Patient Numbers and Trend Data

- a. The middle two pulse bars flash., indicating the monitor is in "trend view" mode. The two pulse bars continue to flash until the mode is exited.
- b. The current patient number is shown for a few seconds.
- c. The last valid data for the corresponding patient number is shown in the  $SpO_2$  and pulse rate displays. If no valid data was collected, "- -" is shown.
- d. Pressing the ▲ or ▼keys will increase or decrease the patient number; the patient number will be shown for a few seconds then the last valid data corresponding to the patient number will be shown.
- e. To exit the "trend view" mode, press the I.D./CLEAR key.

NOTE! If no keys are pressed for 20 seconds, the monitor automatically exits the "trend view" mode.

#### **Clearing Trend Data**

- 1. The  $SpO_2$  sensor must be connected to the monitor. If necessary, connect the  $SpO_2$  sensor to the monitor.
- 2. Press and hold the I.D./CLEAR key for about six seconds. While you are holding the I.D./CLEAR key, the message Lir flashes on the display to tell you the trend data for all patients is about to be cleared. When the trend data is cleared, the display shows P 1.

# **Chapter 7: Printer**

#### Description

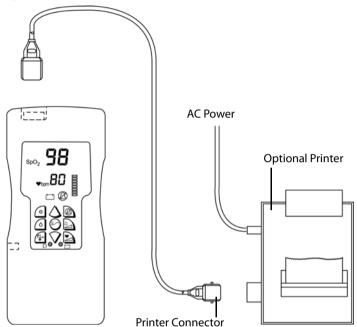


Figure 7-1: Setting Up the Oximeter and the Printer

Data can be printed in trend data mode. In this mode up to 24 hours of previously stored data, collected from 1 to 99 patients, is printed.

Whenever the monitor is on, it stores one SpO<sub>2</sub> and pulse rate reading every thirty (30) seconds.

- If less than 15 minutes of data is collected for one patient, the trend data is printed in a tabular format if 123 mode is selected.
- If more than 15 minutes of data is collected for one patient, the trend data is printed in a graphic format if **LLL** mode is selected.

The monitor remembers trend data for up to 99 patients and 24 hours of run-time. The trend data can be printed at any time on the optional printer.

# Selecting Print Mode For Trend Data

- Keep the ALARM SEL key pressed for 5 seconds. 123 or LLL appears in the SpO<sub>2</sub> display.
- 2. **123** = numerical print-out
- LLL = graphic print-out (only possible with Seiko DPU 201 GSU or Seiko DFU 411 S printers).
- 4. Select mode with arrow key. The selection remains stored and will apply when the monitor is next switched on.
- To return to measurement press ALARM SEL key once.

If a key is not pressed within 20 seconds, the monitor automatically returns to measurement.

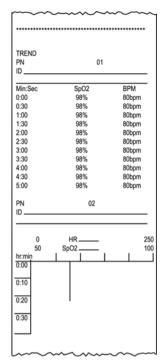


Figure 7-2: Sample Trend Printout

#### **Compatible Printers**

#### Printer requirements:

FUNCTION	SPECIFICATION
I/O Port	Serial RS-232C
Data Type	ASCII
Data Format	9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
I/O Connector	Standard DB-9
Graphics Interface	Seiko Printer Graphics Interface

#### **Compatible Printers:**

MANUFACTURER	MODEL NUMBER
Seiko	DPU-201GSU
	DPU-411-21BU (120 V 60 Hz)
Seiko	DPU-411-21BE (220 V 50 Hz)
	NOTE: A DB-9 to DB-25 pin adapter will be required.

For information on printers and printer accessories, contact your authorized sales representative.

# What You'll Need for Printing

You'll need these items to print trend printouts:

- Oximeter
- Printer Cable (see the *Optional Supplies and Accessories* section for ordering information).
- Compatible printer (purchased from one of the printer manufacturer's distributors).
- Accessories required for the printer, such as paper, power supply or charger, and so on (purchased from the printer manufacturer's distributor).

### Setting Up the Monitor and the Printer

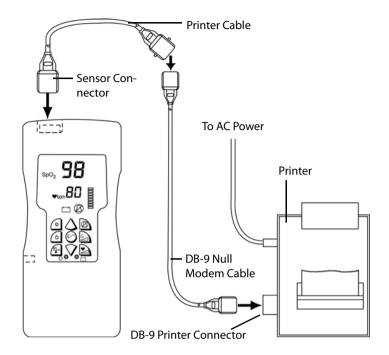


Figure 7-3: Setting Up the Oximeter and the Printer

- 1. Refer to the printer's operation manual and make sure the printer's RS-232 data format is set up as follows:
  - Data Type: ASCII
  - Data Format: 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
- 2. Connect the printer adapter's connector to the sensor connector.
- 3. Connect the printer adapter's DB-9 connector to the mating connector on the printer. (If necessary, connect the printer adapter's DB-9 connector to a DB-9 to DB-25 adapter, then connect the adapter to the printer.)
- 4. Connect the printer's power source to the printer as described in the printer's operation manual.
  - CAUTION! Use only the printer cable specifically intended for use with this device (see *Optional Supplies and Accessories*).
- 5. Make sure the printer has paper loaded and is ready to print as described in the printer's operation manual.

#### **Trend Printouts**

#### **Collecting Trend Data**

Whenever the monitor is on, it stores one  $SpO_2$  and one pulse rate reading every thirty (30) seconds. The stored readings are called *trend* data. The monitor remembers trend data for up to 99 patients and 24 hours of run-time. The trend data can then be printed at any time on the optional printer.

Trend data is saved for each patient number. When you turn on the monitor, the patient number is automatically incremented and displayed during the power-up sequence if valid trend data was collected from the previous patient. If no valid trend data was collected from the previous patient, the patient number is displayed only and is not incremented. The monitor remembers all the trend data and all the patient numbers for up to 99 patients and 24 hours of run-time.

#### **Manually Incrementing the Patient Number**

- 1. The SpO<sub>2</sub> sensor must be connected to the monitor. If necessary, connect the SpO<sub>2</sub> sensor to the monitor.
- 2. Press the I.D./CLEAR key to increment the patient number. The new patient number is momentarily displayed and trend data for the new patient is automatically saved.

#### **Clearing Trend Data**

- 1. The SpO<sub>2</sub> sensor must be connected to the monitor. If necessary, connect the SpO<sub>2</sub> sensor to the monitor.
- 2. Press and hold the I.D./CLEAR key for about six seconds. While you are holding the I.D./CLEAR key, the message **Lir** flashes on the display to tell you the trend data for all patients is about to be cleared. When the trend data is cleared, the display shows **P !**.

#### **Printing Trend Data**

- 1. Set up the monitor and printer as previously described.
- Disconnect the SpO<sub>2</sub> sensor from the monitor.
- 3. Connect the printer cable to the monitor.
- 4. Turn on the printer.
- Turn on the monitor. The monitor prints the trend data for each patient, from patients 1-99, as shown in the sample printout.
- 6. If there is no trend data at all, the message "\*\*\*\*\*\*" is printed.
- 7. If no valid data is collected for a patient number, "\*\*\*\*" is printed.
- 8. If valid data is collected for a patient number for less than one minute, only the last measurement is printed.
- 9. If data is collected for a patient number for more than one minute, the relative time since the first measurement is shown for that patient.

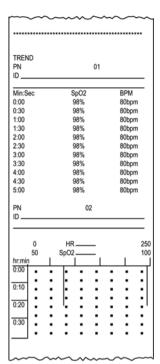


Figure 7-4: Printing Trend Data

- 10. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO<sub>2</sub> sensor).
- 11. Pressing the I.D./CLEAR key increments the patient number, and trend data is collected for the new patient number.

NOTE! If unexpected characters or question marks are printed, turn the printer off and on to reset the printer.

# **Chapter 8: Operating Modes**

#### **About the Monitor's Operating Modes**

The monitor has three operating modes: clinician mode (previously described), home-use mode and sleep study mode.

- The clinician mode is intended for health-care professionals trained in monitoring respiratory and cardiovascular activity.
- The home-use mode is intended for caregivers trained in oximeter use by a doctor or other health-care professional.
- The sleep study mode is intended for health-care professionals trained in monitoring respiratory and cardiovascular activity.

While the monitor is in the clinician mode, all monitor functions operate as described previously in this manual.

NOTE! Accessing Home Use Mode and Sleep Study Mode may only be done from the Clinician Mode. It is not possible to access Home Use Mode from Sleep Study Mode or vice versa.

#### Home Use Mode

While the monitor is in home-use mode:

- Alarm limits can be viewed but cannot be changed.
- The alarm and alert tone is set to loud and cannot be changed.
- Alarm and alert tones can be silenced for two minutes but cannot be silenced indefinitely.
- SpO<sub>2</sub> averaging is set to 8 beats; pulse rate averaging is set to 8 seconds.
- Patient numbers and trend view are disabled.
- Trend data is collected for one patient.
- Trend data from the patient can be printed. The printout is the same as during clinician mode, except "Home Mode" replaces "Patient Number" on the printout.
- All other functions of the monitor work as in clinician mode.

#### Setting Up the Monitor for Home-Use

- 1. Set the high and low alarm limits for SpO<sub>2</sub> and pulse rate to the values prescribed by the doctor:
  - High SpO<sub>2</sub> alarm limit.
  - Low SpO<sub>2</sub> alarm limit.
  - · High pulse rate alarm limit.
  - Low pulse rate alarm limit.
- 2. Clear trend data if necessary. (Press and hold I.D./CLEAR until P1 is displayed.)
- 3. Put the monitor into the home-use mode as follows (Make sure that the monitor is in Clinician Mode prior to executing the following commands!):
  - a. Turn off the monitor.
  - b. Press and hold the ALARM VOL key, then press the ON key.
  - c. While holding the ALARM VOL key, H flashes in the pulse rate display.
  - d. When H stops flashing and lights steady (in about 6 seconds), release the ALARM VOL key. The monitor is now in home-use mode.
- 4. Verify the monitor is in the home-use mode:
  - a. Turn off the monitor.
  - b. Turn on the monitor while observing the display;  $\mu$  should be shown briefly when the monitor is turned on. If not, repeat step 3 above.
- 5. Verify the high and low alarm limits for SpO<sub>2</sub> and pulse rate are set to the values prescribed by the doctor. (Press ALARM SEL to show each of the alarm limits one-at-a-time.)
- 6. Turn off the monitor.

# **Equipment and Supplies Checklist for Home-Use**

Provide the following to the home-use caregiver:

QUANTITY	CAT. NO.	DESCRIPTION
1	3303	Oximeter
1	8210	AC Adapter, 105-125V 60Hz
1	8212	AC Adapter, 230V 50/60Hz
1	8216	AC Adapter, 100V 50Hz
1	3353	Protective rubber boot with carrying case
*	3049	Adhesive Strips (Adhesive Tape)
1	1854	Home-Use Instruction Book
* Quantity prescribed by doctor.		

The doctor will prescribe the type and quantity of the sensors needed for home-use:

QUANTITY	CAT. NO.	DESCRIPTION
*	3044	Sensor, Reusable, Finger
*	3178	Sensor, Pediatric, Finger
1	3311	Cable, Oximetry, 5 Feet
*	3444	Sensor, Comfort Clip
*	1300	Sensor, Disposable, Adult
*	1301	Sensor, Disposable, Pediatric
*	1302	Sensor, Disposable, Neonate
*	1303	Sensor, Disposable, Infant
*	1310	D.O.T. Sensor, Reusable
* Quantity prescribed by doctor.		

The home-use caregiver will also need these supplies and reference materials:

QUANTITY	DESCRIPTION	
1	Scissors (for trimming adhesive strips or adhesive tape).	
*	Isopropyl alcohol and a soft, clean cloth (or alcohol wipes) for disinfecting monitor and reusable sensor.	
1	Written instructions on how to respond to the monitor's alarms.	
1	Emergency phone numbers for the doctor.	
1	Emergency phone number for the hospital emergency room.	
1	Emergency phone number for local paramedics or police.	
1	Phone number for equipment supplier in case the equipment fails.	
* Quantity prescribed by doctor.		

### **Training the Home-Use Caregiver**

- 1. The home-use caregiver must be trained in CPR.
- 2. Make sure the monitor's alarm limits are properly set and that the monitor is in the home-use mode.
- 3. Inform the caregiver that the oximeter is not to be used as an apnea monitor.
- 4. (Following the Home-Use Instruction Book while teaching these tasks may help you and the caregiver.) Show the home-use caregiver how to:
  - Connect the AC power supply to the monitor.
  - Interpret the POWER and CHARGING lights.

- Visually inspect the sensor and oximetry cable.
- Connect the sensor to the oximetry cable.
- Connect the oximetry cable to the monitor.
- Turn on the monitor.
- Route the cable safely from the patient to the monitor to prevent possible patient strangulation.
- Attach the sensor(s) prescribed by the doctor.
- Measure the SpO<sub>2</sub>, pulse rate, and pulse strength bar graph readings.
- Change the brightness of the display.
- Change the pulse beep volume.
- Turn off the alarm and alert tones for two minutes.
- Turn on the alarm and alert tones.
- Interpret the alarms.
- View the alarm limits.
- Interpret the SENSOR alert.
- Interpret the BATT attention.
- Turn off the monitor.
- 5. Tell the caregiver how to respond:
  - In case of a patient emergency, including what therapy to provide the patient.
  - In case an alarm sounds, including what therapy to provide the patient.
  - In case the sensor alert sounds.
  - In case the batt attention sounds.
  - In case the caregiver has trouble operating the equipment.

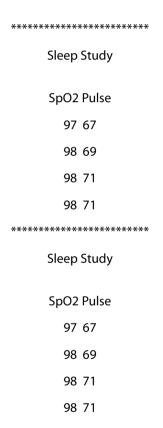
#### **Turning Off Home-Use Mode**

- 1. Turn off the home-use mode (put the monitor into the clinician mode) as follows:
  - a. Turn off the monitor.
  - b. Press and hold the PULSE VOL key, then press the ON key.
  - c. While holding the PULSE VOL key, H flashes in the pulse rate display.
  - d. When H stops flashing, and patient number Pn (n = patient number) lights steady, (in about 6 seconds), release the key. The monitor is now in clinician mode.
- 2. Verify the monitor is in the clinician mode:
  - a. Turn off the monitor.
  - b. Turn on the monitor while observing the display; the software revision then the patient number should be displayed during power-up. If not, repeat step 1 above.

#### Sleep Study Mode

While the monitor is in sleep study mode:

- Patient numbers and trend view are disabled.
- A new trend block is started each time the monitor is turned on.
- Trend data from the patient is stored and may then be output to a PC.
- Following the header, the SpO<sub>2</sub> and pulse rate trend block is output in ASCII as follows:



Each pair of data points represents a four second block of data. For each trend block, the header "Sleep Study" appears preceding the trend block, indicating that a break has occurred in the data.

#### Chapter 8: Operating Modes

- Trend data from the patient is stored every four seconds. The SpO<sub>2</sub> data consists of a minimum display value over the four second interval. Refer to the *Turning on the Monitor* section for information on SpO<sub>2</sub> and pulse rate display values (specifically "averaging"). Since patient ID numbers are disabled in sleep study mode, the trend printout will have the header "Sleep Study" (as shown above) for each patient block. New patient blocks may only be accessed when the unit is turned off, then on.
- When trend memory is full (i.e. after approximately 12 hours of operation), the data storage will begin at the start of memory, thereby overwriting the oldest data (the most recent data is always retained).
- The serial communication setup is the same as in the clinician mode (9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity).
- All other functions of the monitor work as in the clinician mode.

#### Setting Up the Monitor for Sleep Study Mode

NOTE! When entering or exiting Sleep Study mode previous memory will be lost.

- 1. Put the monitor into the sleep study mode as follows (Make sure that the monitor is in Clinician Mode prior to executing the following commands!):
  - a. Turn off the monitor.
  - b. Press and hold the ALARM SEL key, then press the ON key.
  - c. While holding the ALARM SEL key, **5LP** flashes in the pulse rate display.
  - d. When **5LP** stops flashing and lights steady (in about 6 seconds), release the ALARM SEL key. The monitor is now in sleep study mode.
- 2. Verify the monitor is in the sleep study mode:
  - a. Turn off the monitor.

b. Turn on the monitor while observing the display; **5LP** should be shown briefly when the monitor is turned on. If not, repeat step 1 above.

### **Turning Off Sleep Study Mode**

- 1. Turn off the sleep study mode (put the monitor into the clinician mode) as follows:
  - a. Turn off the monitor.
  - b. Press and hold the Alarm Silence key, then press the ON key.
  - c. While holding the Alarm Silence key, **5LP** flashes in the pulse rate display.
  - d. When 5LP stops flashing, and patient number Pn (n = patient number) lights steady, (in about 6 seconds), release the key. The monitor is now in clinician mode.
- 2. Verify the monitor is in the clinician mode:
  - a. Turn off the monitor.
  - b. Turn on the monitor while observing the display; the software revision then the patient number should be displayed during power-up. If not, repeat step 1 above.

### **PC Communication Setup**

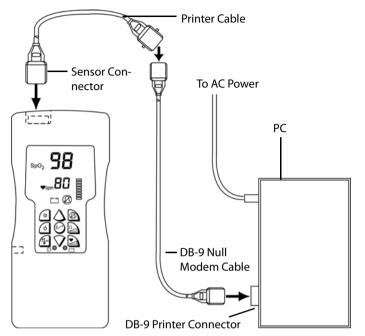


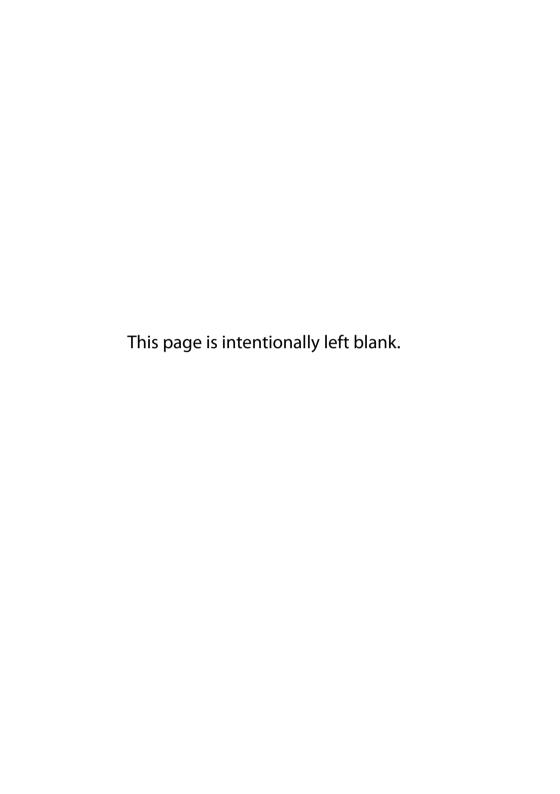
Figure 8-1: Setting Up the Oximeter and the PC

- 1. Power up the monitor.
- 2. Connect the printer communication cable to the monitor.
- 3. Set up the communication software to accept the following RS-232 data format:
  - Data Type: ASCII
  - Data Format: 9600 baud, 1 start bit, 8 data bits, 1 stop bit, no parity
- 4. Connect the standard RS232 null modem cable's DB-9 connector to the mating connector of the printer cable.
- 5. Connect the standard RS232 null modem cable's DB connector to the mating connector on the PC.

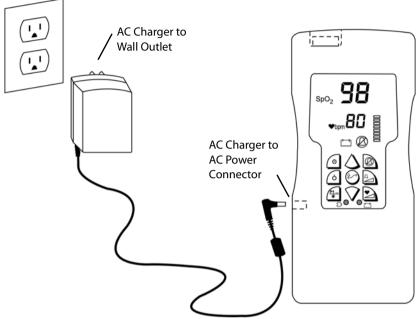
NOTE! The modem cable is an industry standard RS232 modem cable.

#### Transferring Sleep Study Data to a PC

- 1. Set up the monitor, cables, and PC as previously described.
- 2. Turn on the PC and load the communication software, setting the serial communication defaults as previously described.
- 3. Turn on the monitor.
- 4. Dashes indicate invalid or unavailable data (for example, the patient's finger was removed from the SpO<sub>2</sub> sensor).



# **Chapter 9: Charging the Monitor**



- Figure 9-1: Connecting AC Power
- Connect the AC charger as shown. Refer to Chapter 12, Optional Supplies and Accessories, to verify the proper AC power supply for your application.
- 2. Make sure the POWER indicator lights up on the charger. If not, see the *Troubleshooting* section.
- 3. CHGING indicator lights while the monitor's battery is charging.
- 4. Device is fully charged when the CHGING light turns off.
- 5. The monitor's battery will fully charge in about four 4 hours (NiCad) or 6 hours (NiMH). A fully charged battery provides approximately 12 hours (NiCad) or 24 hours (NiMH) of use.

6. The device may be operated while charging.

CAUTION! Ensure the device's AC rating is correct for the AC voltage at your installation site before using this monitor. The monitor's AC rating is shown on the external power supply. If the rating is not correct, do not use the monitor; contact the Smiths Medical PM, Inc. service department, or your local distributor, for help.

CAUTION! Monitors not in use must be fully charged at least every five months, otherwise the battery will no longer be able to accept a charge.

# **Chapter 10: Maintenance**

#### Schedule of Maintenance

MAINTAIN THIS ITEM:	HOW OFTEN:	BY DOING THIS:
Battery	When BATT is flashing, or after the monitor has been used under battery power.  Monitors in storage or not in use must be fully charged at least every 5 months.	Follow the instructions for charging the monitor.
Repositioning the sensor	At least once every 4 hours.	Follow the instructions for attaching the sensor.
Disinfecting the #3044 reusable sensor	Before attaching the sensor to the patient.	Follow the instructions for attaching the #3044 reusable sensor.
Disinfecting the monitor and the AC power sup- ply	When necessary.	1. Disconnect the monitor from the AC power supply. 2. Disconnect the AC power supply from the wall outlet and from the monitor. 3. Wipe the surfaces of the monitor and the AC power supply with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet.  CAUTION! Do not allow isopropyl alcohol to enter any of the openings on the monitor.

#### Correcting the SENSOR Alert

Follow these steps to correct the sensor alert:

- Make sure the sensor's connector is firmly seated in the monitor's connector.
- Make sure the sensor is properly attached to the patient. See Attaching the Sensor to the Patient section for help.
- 3. Make sure the adhesive tape used to hold the sensor is not wrapped too tightly. Wrapping the tape too tightly may prevent the monitor from measuring the  $SpO_2$  and pulse rate.
- 4. If the sensor alert is still on, contact your doctor or the equipment dealer for help.

# **Chapter 11: Troubleshooting**

PROBLEM:	POSSIBLE CAUSE / SOLUTION:	
SENSOR alert.	1. Sensor may not be properly connected to monitor. Make sure sensor connector is firmly seated in monitor connector.  2. Sensor may not be properly attached to patient. See Attaching the Sensor to the Patient.  3. Adhesive tape may be too tight on patient. Loosen adhesive tape.  4. Sensor, interface cable, or monitor may be defective. Contact authorized repair center for help.	
BATT attention.	Monitor's battery has become weak from use. See <i>Charging the Monitor</i> :	
SpO <sub>2</sub> , pulse rate, or pulse bar graph not shown on monitor. or Pulse rate value erratic, intermittent, or incorrect. or SpO <sub>2</sub> value erratic, intermittent, or incorrect.	<ol> <li>Patient may be moving. Have patient remain as still as possible.</li> <li>Connectors from sensor to monitor may not be firmly seated. Make sure all connectors between sensor and monitor are firmly seated.</li> <li>Sensor may not be properly attached to patient. See Attaching the Sensor to the Patient.</li> <li>Adhesive tape may be too tight on patient. Loosen adhesive tape.</li> <li>Sensor, interface cable, or monitor may be defective. Contact authorized repair center for help.</li> </ol>	
Monitor does not turn on when ON key is pressed.	Battery needs charging. See <i>Charging the Monitor</i> .     Monitor may be defective. Contact authorized repair center for help.	

# Chapter 11: Troubleshooting

Monitor turns off suddenly.	Battery needs charging. See Charging the Monitor.
POWER indicator does not light when AC power supply is attached.	1. Make sure the AC power supply is firmly connected to the wall outlet and to the monitor.  2. Make sure the wall outlet is not controlled by a switch.  3. Make sure AC power is available at the wall outlet. (Plug a lamp or a radio into the same wall outlet and see if the lamp or radio turns on.)  4. AC power supply or monitor may be defective. Contact authorized repair center for help.
CHGING does not light on the monitor.	1. Monitor's battery may be charged.
No printout on optional printer.	<ol> <li>Printer power not connected, or printer power switch is off. Make sure the power is connected to the printer and the printer power switch is on.</li> <li>Printer interface connectors not firmly seated. Make sure printer interface cables are firmly seated.</li> <li>Insure that the proper communication protocol has been selected for the printer.</li> <li>Printer or monitor may be defective. Contact authorized repair center for help.</li> </ol>

# **Chapter 12: Optional Supplies and Accessories**

CAT. NO.	DESCRIPTION	QTY.
1300	Sensor, Oximetry, Disp., Adult Finger	10/box
1301	Sensor, Oximetry, Disp., Ped. Finger, 15-45 Kg	10/box
1302	Sensor, Oximetry, Disp., Neonate, < 3 Kg	10/box
1303	Sensor, Oximetry, Disp., Infant, 3-15 Kg	10/box
1310	D.O.T. Reusable Oximetry Sensors	3/box
1311	D.O.T. Sensor Replacement Tape	24/pkg
1606	Simulator	each
1850	Manual, Clinician's Operation (Oximeter)	each
1851	Manual, Service (Oximeter)	each
1854	Manual, Home Use Instruction Book (Oximeter)	each
3025	Sensor, Oximetry, Wrap, Infant, 3-15 Kg	each
3026	Sensor, Oximetry, Wrap, Neonate, < 3 Kg	each
3043	Sensor, Oximetry, Universal "Y"	each
3044	Sensor, Oximetry, Finger	each
3049	Strips, Adhesive	40/pkg.
3078	Sensor, Oximetry, Ear	each
3134	Tape, Attachment, Neonatal	50/pkg.
3135	Tape, Attachment, Infant	50/pkg.
3136	Tape, Attachment, Neonatal	100/pkg.
3137	Tape, Attachment, Infant	100/pkg.
3138	Posey Wrap, Attachment, Universal "Y"	10/pkg.
3178	Sensor, Pediatric, Finger	each
3311	Cable, Oximetry, 5 ft.	each
3350	Printer Cable (for #3303)	each
3353	Protective rubber boot with carrying strap	each
3354	Pole Mount Bracket	each
3444	Sensor, Oximetry, Finger, Comfort Clip	each
8210	AC Power Supply, 105-125V 60Hz	each
8212	AC Power Supply, 230V 50/60Hz	each
8216	AC Power Supply 100V 50Hz	each

# **Ordering Information**

For ordering information, contact your local distributor or the Smiths Medical PM, Inc. customer service department.

Smiths Medical PM, Inc.
N7 W22025 Johnson Drive
Waukesha, WI 53186 USA
Phone: 262 542 3100
Fax: 262 542 3325

Email Address: info@smiths-bci.com

# **Chapter 13: Specifications**

#### Oximeter

Parameters Monitored	SpO <sub>2</sub> Pulse Rate Pulse Strength	
Displays, Indicators, & Keys	SpO <sub>2</sub> 3-digit LED display, 0.43 inches (10.9 mm) high.	
	Pulse Rate	3-digit LED display, 0.375 inches (9.5 mm) high.
	Pulse Strength	Logarithmically scaled 8-segment LED bar graph.
	SENSOR	Sensor alert indicator.
	BATT	Low battery indicator.
	Silenced	Alarm and alert tone silenced indicator.
	Keys	Nine control keys provided.
	Brightness	Adjustable brightness of SpO <sub>2</sub> , pulse rate, and bar graph displays.
Indicators	POWER	Indicates oximeter connected to AC power.
	CHGING	Indicates oximeter battery is charging.
SpO <sub>2</sub>	Range	0-100%
	Accuracy	±2% at 70-100% ±3% at 50-69%
	Alarm Limits	High 100-50% and off in 1% steps. Low 50-99% and off in 1% steps.
	Averaging	4, 8, or 16 pulse beat average.
Sensors	Red Infrared	660nm, 2mW (typical) 905nm, 2-2.4mW (typical)

Pulse Rate	Range	30-254 BPM			
	Accuracy	±2% at 30-254 BPM			
	Alarm Limits	High 250-5 BPM and off in 5 BPM steps. Low 5-250 BPM and off in 5 BPM steps.			
	Averaging	8 or 16 second average.			
Alarm Indicators	Two-tone audible alarm with user-adjustable volume and two-minute or indefinite alarm silence. Corresponding numeric display flashes.				
Sensor Alert Indicator	Single-tone audible alarm with same volume and silence as alarm tone.				
Printer Output	Data saved every thirty (30) seconds can be printed (trend).				
Battery	Туре	Internal rechargeable NiCad or NiMH; not user replaceable.			
	Charge Time	Nicad: Fully charges in about 4 hours. NiMH: Fully charges in about 6 hours.			
	Use Time	Approximate continuous use: 12 hours (Nicad) 24 hours (NiMH).			
	Indicators	BATT indicator lights when about 30 minutes of battery use remains.			
AC Charger	Wall Mount Style	Input of 105-125 V~, 60Hz Input of 100V~, 50Hz (Optional)			
	Table Top Style	Input of 230 V~, 50/60Hz			
Dimensions	Width	3.3 inches (84 mm)			
	Height	7.25 inches (184 mm)			
	Depth	1.85 inches (47 mm)			
	Weight	19 ounces (539 grams) including battery			
Environmental Specifications	Temperature	Operating:-20-55° C (-4-131° F) Storage: -40-75° C (-40-167° F)			
	Relative Humidity	Operating: 15-95%, non-condensing Storage: 10-90%, non-condensing			



# Smiths Medical PM, Inc. Patient Monitoring and Ventilation



Authorized Representative (as defined by the Medical Device Directive):

Smiths Medical International Ltd. Phone: (44) 1923 246434 Colonial Way, Watford, Herts, Fax: (44) 1923 240273

UK, WD24 4LG